

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
20 June 2002 (20.06.2002)

PCT

(10) International Publication Number
WO 02/47539 A2

(51) International Patent Classification⁷: **A61B**

(21) International Application Number: PCT/US01/48757

(22) International Filing Date:
14 December 2001 (14.12.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/256,196 15 December 2000 (15.12.2000) US

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(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

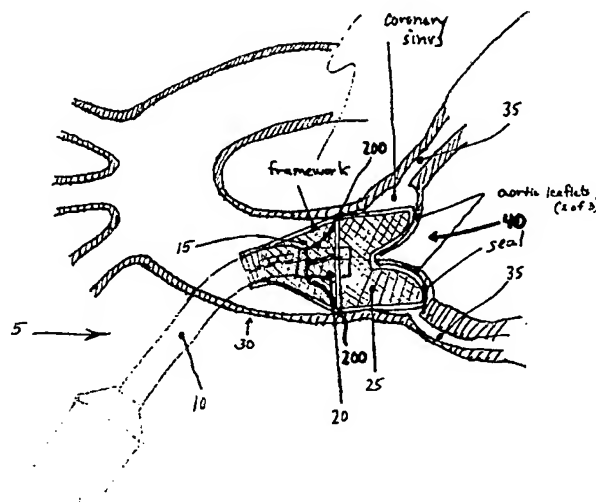
(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— without international search report and to be republished upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: APPARATUS AND METHOD FOR REPLACING AORTIC VALVE



(57) Abstract: Apparatus and methods are disclosed for performing beating heart surgery. Apparatus is disclosed comprising a cannula having a proximal end and a distal end; an aortic filter in connection with the cannula, the aortic filter having a proximal side and a distal side; a check valve in connection with the cannula, the check valve disposed on the distal side of the aortic filter; and a coronary artery filter in connection with the cannula, the coronary artery filter having a proximal end and a distal end, and the distal end of the coronary artery filter extending distally away from the distal end of the cannula. A method is disclosed comprising providing apparatus for performing beating heart surgery; deploying the apparatus in an aorta; performing a procedure on the aortic valve; and removing the apparatus from the aorta.

APPARATUS AND METHOD FOR REPLACING AORTIC VALVEReference To Pending Prior Patent Application

This patent application claims benefit of pending prior U.S. Provisional Patent Application Serial No. 60/256,196, filed 12/15/00 by Richard B. Streeter for APPARATUS AND METHOD FOR REPLACING AORTIC VALVE (Attorney's Docket No. VIA-15 PROV), which patent application is hereby incorporated herein by reference.

Field Of The Invention

This invention relates to apparatus and methods for performing cardiac surgery in general, and more particularly to apparatus and methods for performing cardiac surgery while the heart is beating.

Background Of The Invention

In many cases, surgery must be performed on the heart. Under most circumstances, the heart is stopped

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while this surgery is performed, and the patient is kept alive during surgery through the use of a so-called "heart-lung machine". This type of surgery is frequently referred to as "on pump" surgery.

However, it has been recognized that the use of a heart-lung machine can have serious deleterious effects on the patient. Therefore, interest has become widespread in conducting so-called "off pump", or "beating heart", coronary artery bypass surgery. In this type of procedure, the bypass surgery is conducted while the patient's heart continues to beat. While this type of surgery can be significantly more difficult for the surgeon, the advantages can also be sufficiently great for the patient. As a result, a substantial percentage of bypass procedures are now done off pump.

However, for some types of procedures, e.g., aortic valve replacement, it can be effectively impossible to conduct the required surgery off pump using conventional apparatus and methods.

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However, in pending PCT Patent Application No. PCT/US00/02126, filed 01/27/00 by Viacor Incorporated for CARDIAC VALVE PROCEDURE METHODS AND DEVICES (Attorney's Docket No. 56322/VIAL-115PC/VIA-3 PCT), which patent application is hereby incorporated herein by reference, there is disclosed a novel apparatus and method for conducting off pump aortic valve replacement. In this patent application there is disclosed, among other things, apparatus comprising a temporary valve and filter which is placed in the aorta downstream from the defective aortic valve and which can effectively replace the functionality of the defective aortic valve while that valve is resected and replaced, and which also prevents debris from the valve resection from passing downstream during the resection procedure.

One object of the present invention is to provide a novel apparatus and method for providing improved protection for the coronary arteries during valve resection.

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Another object of the present invention is to provide a novel apparatus and method for providing improved coronary perfusion during valve resection.

Another object of the present invention is to provide, in a single apparatus, used through a single point of entry, (1) a check valve for ensuring unidirectional flow of blood from the heart to the circulatory system, (2) filtration mechanisms for preventing debris from passing down the coronary arteries and/or the aorta, (3) apparatus to augment coronary perfusion, and (4) apparatus for passing instruments from the incision site to the heart.

Summary Of The Invention

These and other objects are achieved through the provision and use of novel apparatus which, in one preferred form of the invention, comprises a cannula; an aortic filter connected to the cannula; a check valve connected to the cannula distally of the aortic filter; and a coronary artery filter connected to the cannula and extending distally of the check valve.

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During use, the apparatus is deployed in the aorta so that the coronary artery filter covers the openings (coronary ostia) of the coronary arteries, the check valve is deployed downstream from the coronary artery filter, and the aortic filter is deployed downstream from the check valve. Among other things, in addition to delivering the aortic filter, check valve and coronary artery filter to the surgical site and supporting them there, the cannula also permits the delivery of instruments to the surgical site.

In another preferred embodiment, the device further comprises one or more passageways for perfusing the coronary arteries with filtered blood, especially during diastole.

Brief Description Of The Drawings

These and other objects and features of the present invention will be more fully disclosed or rendered obvious by the following detailed description of the preferred embodiments of the invention, which are to be considered together with the accompanying

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drawings wherein like numbers refer to like elements and further wherein:

Fig. 1 is a schematic drawing showing a first embodiment of the present invention deployed adjacent to the aortic valve of the heart;

Fig. 2 is a schematic drawing showing a second embodiment of the present invention deployed adjacent to the aortic valve of the heart;

Fig. 2A is a schematic drawing showing details of the apparatus shown in Fig. 2;

Fig. 3 is a schematic drawing showing a third embodiment of the present invention deployed adjacent to the aortic valve of the heart;

Fig. 4 is a schematic drawing showing a fourth embodiment of the present invention deployed adjacent to the aortic valve of the heart; and

Fig. 5 is a schematic drawing showing a fifth embodiment of the present invention deployed adjacent to the aortic valve of the heart.

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Detailed Description Of The Preferred Embodiments

All configurations of the present invention are generally believed to require a seal between the apparatus and the blood flow path to ensure all blood is filtered during systole and the blood flow is blocked during diastole for apparatus configurations that include a temporary check valve to replace the function of the aortic valve. During systole, the seal against the periphery of the aortic valve need not hold back much pressure since the check valve provides very little resistance to blood flow and debris tends to follow laminar flow through the device and valve. During diastole, the check valve closes and the seal between the device and the blood flow path must hold back the diastolic pressure. Blood leaking through the device during diastole is called peri-valvular leakage and blood leaking around the device is called peri-prosthetic leakage. The present invention provides several configurations for sealing during systole and diastole.

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Looking first at Fig. 1, there is shown an apparatus 5 which comprises a first preferred embodiment of the present invention. Apparatus 5 generally comprises a cannula 10; an aortic filter 15 connected to cannula 10; a check valve 20 connected to cannula 10 distally of aortic filter 15; and a coronary artery filter 25 connected to the cannula and extending distally of check valve 20. Among other things, in addition to delivering the aortic filter, check valve and coronary artery filter to the surgical site and supporting them there, the cannula also permits the delivery of instruments to the surgical site. If desired, coronary artery filter 25 may have a different porosity than aortic filter 15. By way of example but not limitation, coronary artery filter 25 may have a larger mesh size than aortic filter 15. Apparatus 5 is configured so that it will make a substantial seal with aorta 30 at 200.

During use, apparatus 5 is deployed in aorta 30 so that coronary artery filter 25 covers the openings of the coronary arteries 35 and seals against the

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periphery of the aortic valve, check valve 20 is deployed downstream from coronary artery filter 25, and aortic filter 15 is deployed downstream from check valve 20. As a result of this construction, during systole, blood can pass into the aorta, past check valve 20 and past aortic filter 15. Correspondingly, during diastole, blood will be prevented from passing back through check valve 20. Furthermore, aortic valve 40 may be safely resected with apparatus 5 in place, since (i) during systole, aortic filter 15 will prevent debris from the resection from passing down aorta 30, and (ii) during systole or diastole, coronary artery filter 25 will prevent debris from passing down coronary arteries 35.

Looking next at Figs. 2 and 2A, there is shown an apparatus 5A which comprises a second preferred embodiment of the invention. Apparatus 5A generally comprises a cannula 10; an aortic filter 15A connected to cannula 10; a check valve 20 connected to cannula 10 distally of aortic filter 15A; and a coronary artery filter 25A connected to the cannula and

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extending distally of check valve 20. Among other things, in addition to delivering the aortic filter, check valve and coronary artery filter to the surgical site and supporting them there, the cannula also permits the delivery of instruments to the surgical site. If desired, coronary artery filter 25A may have a different porosity than aortic filter 15A. By way of example but not limitation, coronary artery filter 25A may have a larger mesh size than aortic filter 15A. In addition to the foregoing, coronary artery filter 25A includes a plurality of impermeable membranes 26A extending longitudinally along coronary artery filter 25A. The proximal ends of impermeable membranes 26A are located adjacent to the upstream side of aortic filter 15A. Impermeable membranes 26A serve as liners to channel blood flow to coronary arteries 35 during diastole, as will hereinafter be discussed in further detail. Apparatus 5A is configured so that it will make a substantial seal with aorta 30 about the perimeter of check valve 20, except for the portion of the perimeter adjacent to

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impermeable membranes 26A. In other words, apparatus 5A is configured so that it will make a substantial seal with aorta 30 at 200A in Fig. 2A, but not at 205A in Fig. 2A.

During use, apparatus 5A is deployed in aorta 30 so that the impermeable membranes 26A of coronary artery filter 25A are aligned with, and substantially cover, the openings of the coronary arteries 35 and seals against the periphery of the aortic valve, check valve 20 is deployed downstream from coronary artery filter 25A, and aortic filter 15A is deployed downstream from check valve 20. As a result of this construction, during systole, blood can pass into the aorta, past check valve 20 and past aortic filter 15A. Correspondingly, during diastole, blood will be prevented from passing back through check valve 20. However, blood will be able to pass around check valve 20 by following the channels or passageways defined by impermeable membranes 26A, so that the coronary arteries will be perfused during diastole. Furthermore, aortic valve 40 may be safely resected

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with apparatus 5A in place, since (i) during systole, aortic filter 15A will prevent debris from the resection from passing down aorta 30, and (ii) during diastole, only blood already having passed through aortic filter 15A will be able to pass down coronary arteries 35.

Looking next at Fig. 3, there is shown an apparatus 5B which comprises a third preferred embodiment of the invention. Apparatus 5B generally comprises a cannula 10; an aortic filter 15B connected to cannula 10; a check valve 20B connected to cannula 10 distally of aortic filter 15B; and an impermeable membrane 25B connected to the cannula and extending distally of check valve 20B. Among other things, in addition to delivering the aortic filter, check valve and impermeable membrane to the surgical site and supporting them there, the cannula also permits the delivery of instruments to the surgical site. Aortic filter 15B, check valve 20B and impermeable membrane 25B are all adapted to be spaced, along at least some portion of their circumference, from the surrounding

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wall of aorta 30, whereby to define one or more passageway(s) alongside the apparatus. In addition, impermeable membrane 25B is adapted to make a sealing engagement with the periphery of aortic valve 40, i.e., at 200B in Fig. 3.

During use, apparatus 5B is deployed in aorta 30 so that impermeable membrane 25B engages the periphery of aortic valve 40, check valve 20B is deployed downstream from impermeable membrane 25B, and aortic filter 15B is deployed downstream from check valve 20B. As a result of this construction, during systole, blood can pass into the aorta, past check valve 20B and past aortic filter 15B.

Correspondingly, during diastole, blood will be prevented from passing back through check valve 20 into the heart, but it will be able to pass back to coronary arteries 35 through the aforementioned peripheral passageway(s) established between apparatus 5B and the wall of the aorta. Furthermore, aortic valve 40 may be safely resected with apparatus 5B in place, since (i) during systole, aortic filter 15B

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will prevent debris from the resection from passing down aorta 30, and (ii) during diastole, only blood having already passed through aortic filter 15B will be able to pass down coronary arteries 35.

Looking next at Fig. 4, there is shown an apparatus 5C which comprises a fourth preferred embodiment of the invention. Apparatus 5C generally comprises a cannula 10; an aortic filter 15C connected to cannula 10; a check valve 20C connected to cannula 10 distally of aortic filter 15C; and a coronary artery filter 25C connected to the cannula and extending distally of check valve 20C. Among other things, in addition to delivering the aortic filter, check valve and coronary artery filter to the surgical site and supporting them there, the cannula also permits the delivery of instruments to the surgical site. If desired, coronary artery filter 25C may have a different porosity than aortic filter 15C. By way of example but not limitation, coronary artery filter 25C may have a larger mesh size than aortic filter 15C. In addition to the foregoing, a plurality of

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conduits 27C, formed of impermeable tubular material, are attached downstream of the check valve 20C and extend, distally, parallel to coronary artery filter 25C. Apparatus 5C is configured so that it will make a substantial seal with aorta 30 at 200C.

During use, apparatus 5C is deployed in aorta 30 so that the free ends of conduits 27C are disposed in the coronary arteries 35, possibly by a guided catheter, a guidewire or other delivery mechanism, and coronary artery filter 25C otherwise covers the openings of the coronary arteries 35, check valve 20C is deployed downstream from coronary artery filter 25C, and aortic filter 15C is deployed downstream from check valve 20C. As a result of this construction, during systole, blood can pass into the aorta; past check valve 20C and past aortic filter 15C. Correspondingly, during diastole, blood will be prevented from passing back through check valve 20C. However, blood will be able to pass around check valve 20C by following conduits 27C so that the coronary arteries will be perfused with blood during diastole.

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Furthermore, aortic valve 40 may be safely resected with apparatus 5C in place, since (i) during systole, aortic filter 15C will prevent debris from the resection from passing down aorta 30, and (ii) during diastole, only blood already having passed through aortic filter 15C will be able to pass down coronary arteries 35.

Looking next at Fig. 5, there is shown an apparatus 5D which comprises another preferred embodiment of the present invention. Apparatus 5D comprises a cannula 10 and a filter 100 connected to the cannula and extending distally of the cannula. Among other things, in addition to delivering filter 100 to the surgical site and supporting it there, the cannula also permits the delivery of instruments to the surgical site. Filter 100 is adapted to make a sealing engagement with the periphery of aortic valve 40, i.e., at 200D in Fig. 5.

During use, apparatus 5D is deployed in aorta 30 so that filter 100 covers the aorta and the openings (coronary ostia) of the coronary arteries 35. As a

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result of this construction, during systole, blood will pass through filter 100 before passing down the aorta and/or down the coronary arteries. During diastole, blood will pass through filter 100 before passing down the coronary arteries.

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What Is Claimed Is:

1. Apparatus for performing beating heart surgery, said apparatus comprising:

a cannula having a proximal end and a distal end;
an aortic filter in connection with said cannula, said aortic filter having a proximal side and a distal side;

a check valve in connection with said cannula, said check valve disposed on said distal side of said aortic filter; and

a coronary artery filter in connection with said cannula, said coronary artery filter having a proximal end and a distal end, and said distal end of said coronary artery filter extending distally away from said distal end of said cannula.

2. Apparatus according to claim 1 wherein said cannula permits delivery of an instrument to a surgical site.

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3. Apparatus according to claim 1 wherein the porosity of said coronary artery filter is different from the porosity of said aortic filter.

4. Apparatus according to claim 1 wherein said coronary artery filter has a larger mesh size than said aortic filter.

5. Apparatus according to claim 1 wherein said apparatus is configurable to form a substantial seal with a vascular structure.

6. Apparatus according to claim 5 wherein said vascular structure is an inner surface of an aorta.

7. Apparatus according to claim 1 further comprising at least one impermeable membrane extending longitudinally along a surface of said coronary artery filter.

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8. Apparatus according to claim 7 wherein said at least one impermeable membrane has a proximal end and a distal end in an orientation corresponding to said proximal end of said cannula and said distal end of said cannula, respectively, and said proximal end of said at least one impermeable membrane is connected to said coronary artery filter so as to channel blood flow to a coronary artery during diastole.

9. Apparatus according to claim 1 wherein said coronary artery filter forms a perfusion conduit on a surface thereof so as to allow blood flow to a coronary artery during diastole.

10. Apparatus according to claim 9 further comprising an impermeable membrane extending longitudinally along a surface of said coronary artery filter, wherein said impermeable membrane having a proximal end and a distal end in an orientation corresponding to said proximal end of said cannula and said distal end of said cannula, respectively, and

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said proximal end of said impermeable membrane is connected to said coronary artery filter so as to channel blood flow to said coronary arteries during diastole.

11. Apparatus according to claim 10 wherein said apparatus is configurable to form a substantial seal with an aorta, with said outer surface of said coronary artery filter leaving said perfusion conduit unobstructed.

12. Apparatus for performing beating heart surgery according to claim 1 further comprising at least one conduit having a proximal end and a distal end in an orientation corresponding to said proximal end of said cannula and said distal end of said cannula, respectively, said proximal end of said at least one conduit being positionable to said proximal side of said aortic filter, and said distal end of said at least one conduit being positionable to coronary arteries.

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13. Apparatus for performing beating heart surgery, said apparatus comprising:

a cannula having a proximal end and a distal end;
an aortic filter in connection with said cannula, said aortic filter having a proximal side and a distal side;

a check valve in connection with said cannula, said check valve disposed on said distal side of said aortic filter; and

an impermeable membrane in connection with said cannula, said impermeable membrane having a proximal end and a distal end, and said distal end of said impermeable membrane extending beyond said distal end of said cannula in a direction from said proximal end of said cannula to said distal end of said cannula.

14. Apparatus according to claim 13 wherein said cannula permits delivery of an instrument to a surgical site.

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15. Apparatus according to claim 13 wherein said aortic filter and said impermeable membrane define a passageway on an outer surface thereof so as to allow blood flow to coronary arteries during diastole.

16. Apparatus according to claim 15 wherein said distal end of said impermeable membrane is adapted to make a sealing engagement with a periphery of an aortic valve.

17. Apparatus for performing beating heart surgery, said apparatus comprising:

a cannula having a proximal end and a distal end;
and

a filter in connection with said cannula, said filter having a proximal end and a distal end, said distal end of said filter extending beyond said distal end of said cannula in a direction from said proximal end to said distal end of said cannula;

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wherein said distal end of said filter is adapted to make a sealing engagement with a periphery of an aortic valve.

18. Apparatus according to claim 17 wherein said cannula permits delivery of an instrument to a surgical site.

19. A method for performing beating heart surgery, said method comprising:

providing apparatus for performing beating heart surgery, said apparatus comprising:

a cannula having a proximal end and a distal end;

an aortic filter in connection with said cannula, said aortic filter having a proximal side and a distal side;

a check valve in connection with said cannula, said check valve disposed on said distal side of said aortic filter; and

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a coronary artery filter in connection with said cannula, said coronary artery filter having a proximal end and a distal end, and said distal end of said coronary artery filter extending distally away from said distal end of said cannula;

deploying said apparatus in an aorta;

performing a procedure on the aortic valve; and

removing said apparatus from the aorta.

20. A method for performing beating heart surgery, said method comprising:

providing apparatus for performing beating heart surgery comprising:

a cannula having a proximal end and a distal end;

an aortic filter in connection with said cannula, said aortic filter having a proximal side and a distal side;

a check valve in connection with said cannula, said check valve disposed on said distal side of said aortic filter;

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a coronary artery filter in connection with said cannula, said coronary artery filter having a proximal end and a distal end, and said distal end of said coronary artery filter extending distally away from said distal end of said cannula;

said coronary artery filter comprising a perfusion conduit on an outer surface thereof so as to allow blood flow to said coronary arteries during diastole; and

deploying said apparatus in an aorta;

performing a procedure on the aortic valve; and

removing said apparatus from the aorta.

21. A method for performing beating heart surgery, said method comprising:

providing apparatus for performing beating heart surgery comprising:

a cannula having a proximal end and a distal end;

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an aortic filter in connection with said cannula, said aortic filter having a proximal side and a distal side;

a check valve in connection with said cannula, said check valve disposed on said distal side of said aortic filter; and

an impermeable membrane in connection with said cannula, said impermeable membrane having a proximal end and a distal end, and said distal end of said impermeable membrane extending beyond said distal end of said cannula in a direction from said proximal end of said cannula to said distal end of said cannula;

deploying said apparatus in an aorta;

performing a procedure on the aortic valve; and

removing said apparatus from the aorta.

22. A method for performing beating heart surgery, said method comprising:

providing apparatus for performing beating heart surgery comprising:

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a cannula having a proximal end and a distal end;

an aortic filter in connection with said cannula, said aortic filter having a proximal side and a distal side;

a check valve in connection with said cannula, said check valve disposed on said distal side of said aortic filter;

a coronary artery filter in connection with said cannula, said coronary artery filter having a proximal end and a distal end, and said distal end of said coronary artery filter extending distally away from said distal end of said cannula; and

at least one conduit having a proximal end and a distal end in an orientation corresponding to said proximal end of said cannula and said distal end of said cannula, respectively, said proximal end of said at least one conduit being positionable to said proximal side of said aortic filter, and said distal end of said at least one conduit being positionable into a coronary artery;

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deploying said apparatus in an aorta;
performing a procedure on the aortic valve; and
removing said apparatus from the aorta.

23. A method for performing beating heart surgery, said method comprising:

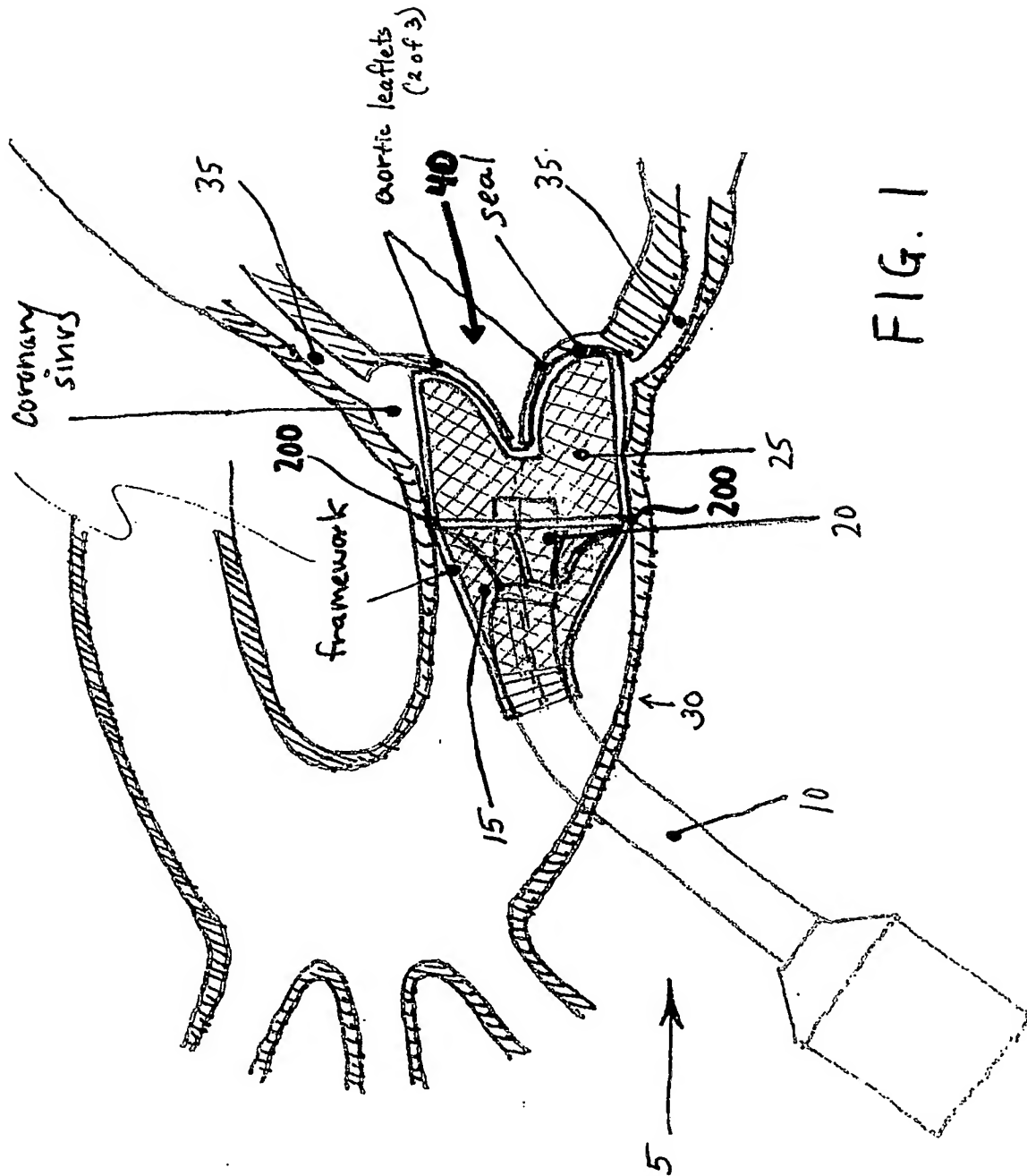
providing apparatus for performing beating heart surgery, said apparatus comprising:

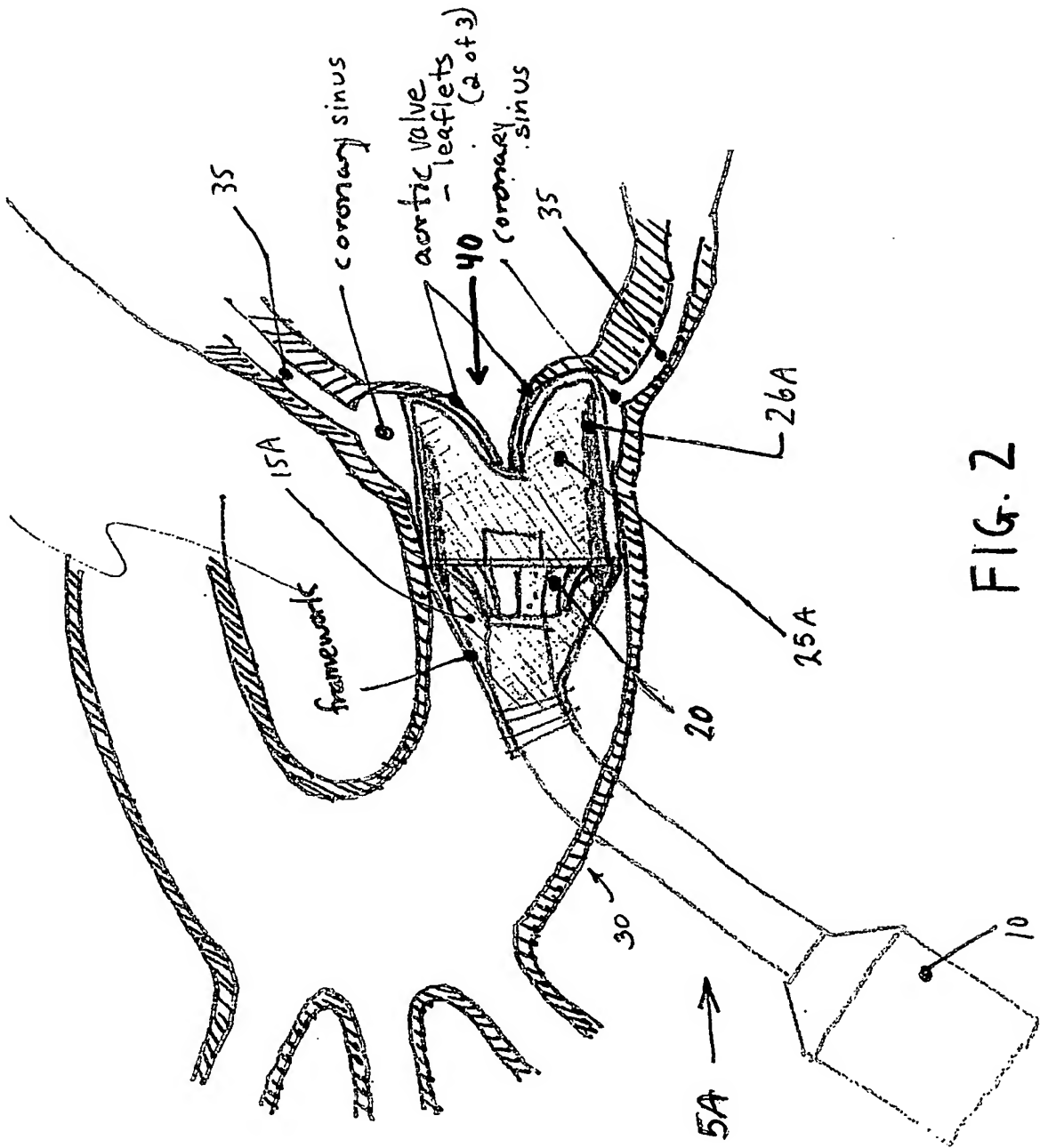
a cannula having a proximal end and a distal end; and

a filter in connection with said cannula, said filter having a proximal end and a distal end, said distal end of said filter extending beyond said distal end of said cannula in a direction from said proximal end to said distal end of said cannula;

wherein said distal end of said filter is adapted to make a sealing engagement with a periphery of an aortic valve;

deploying said apparatus in an aorta;
performing a procedure on the aortic valve; and
removing said apparatus from the aorta.





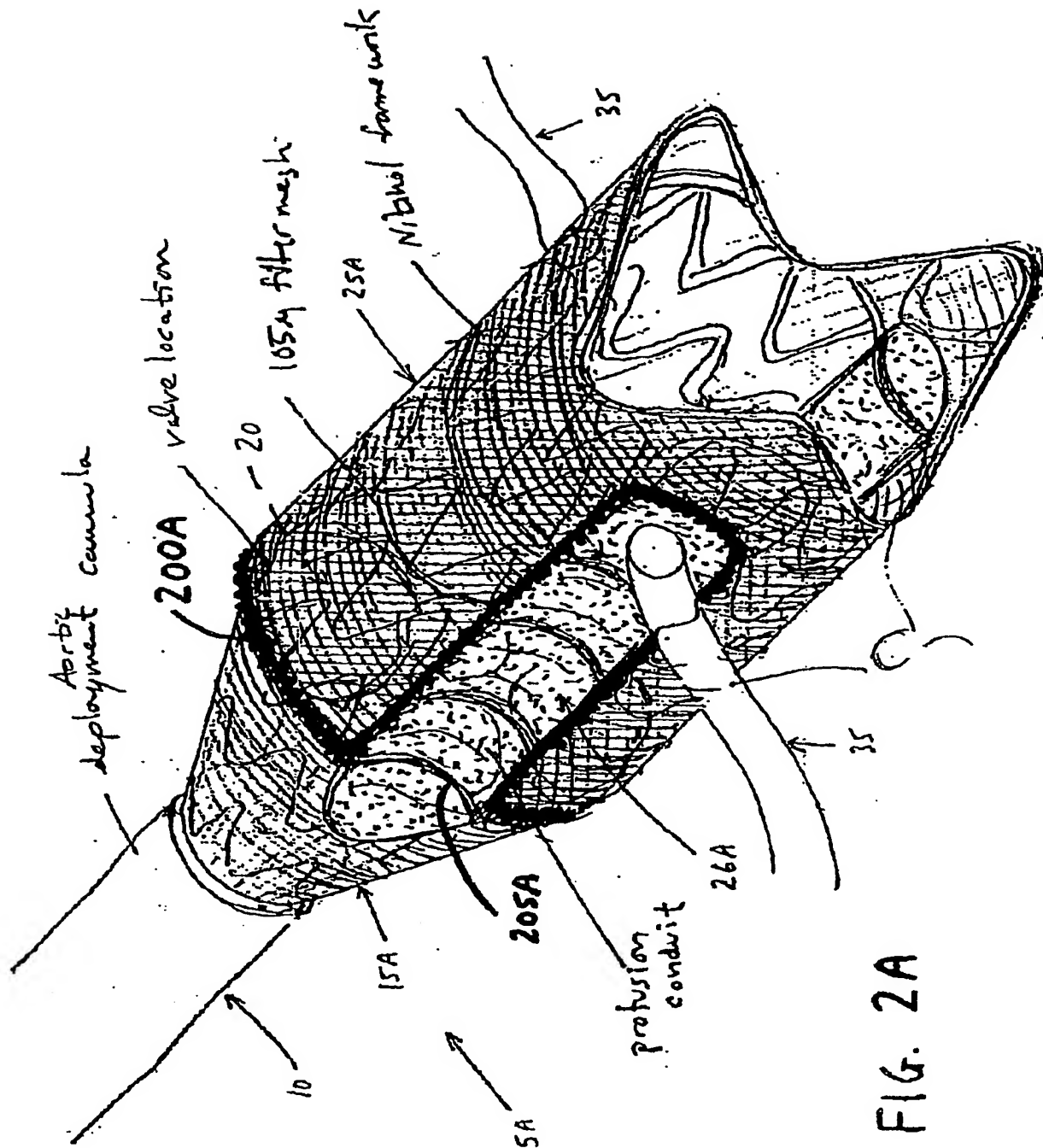


FIG. 2A

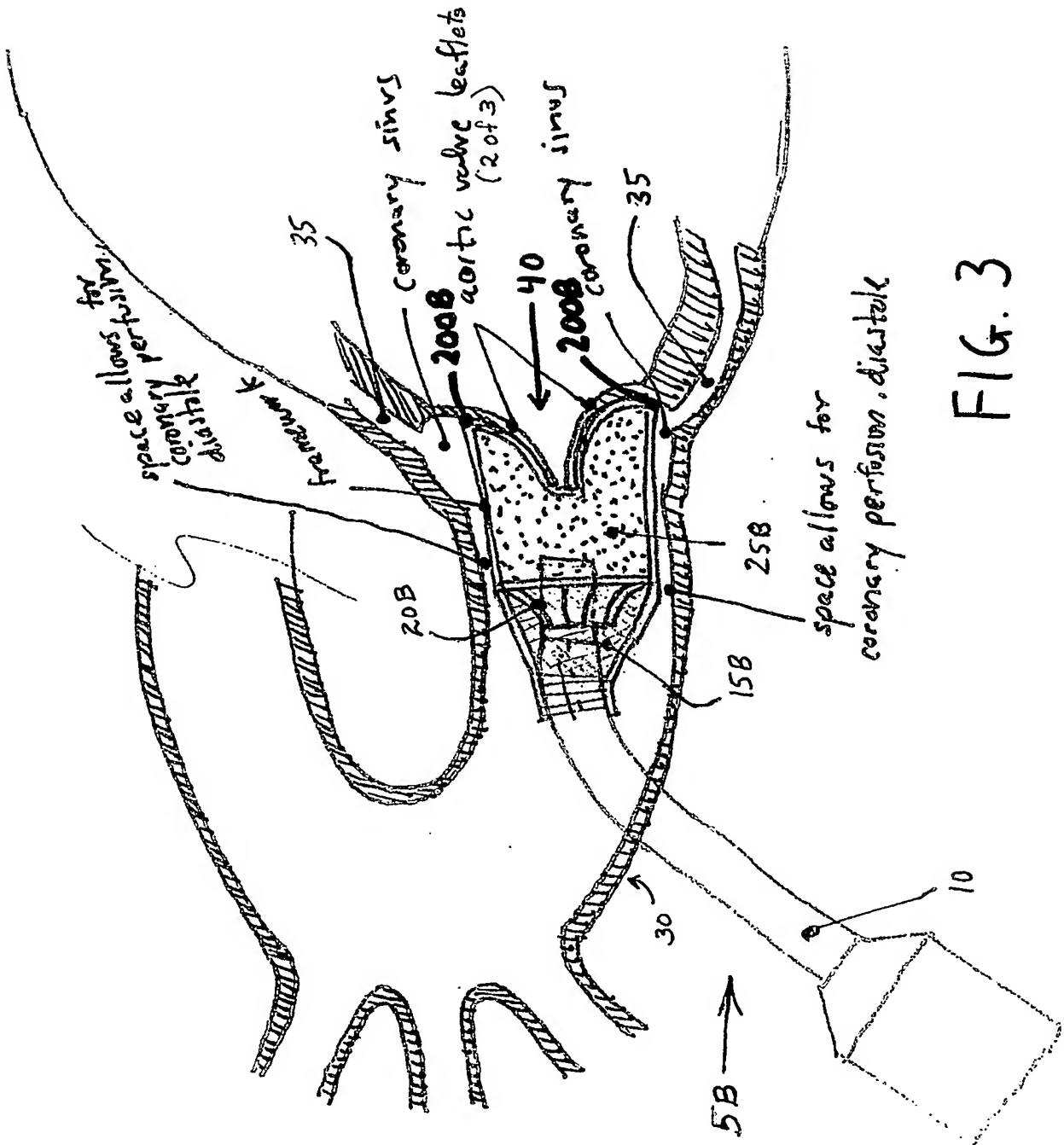
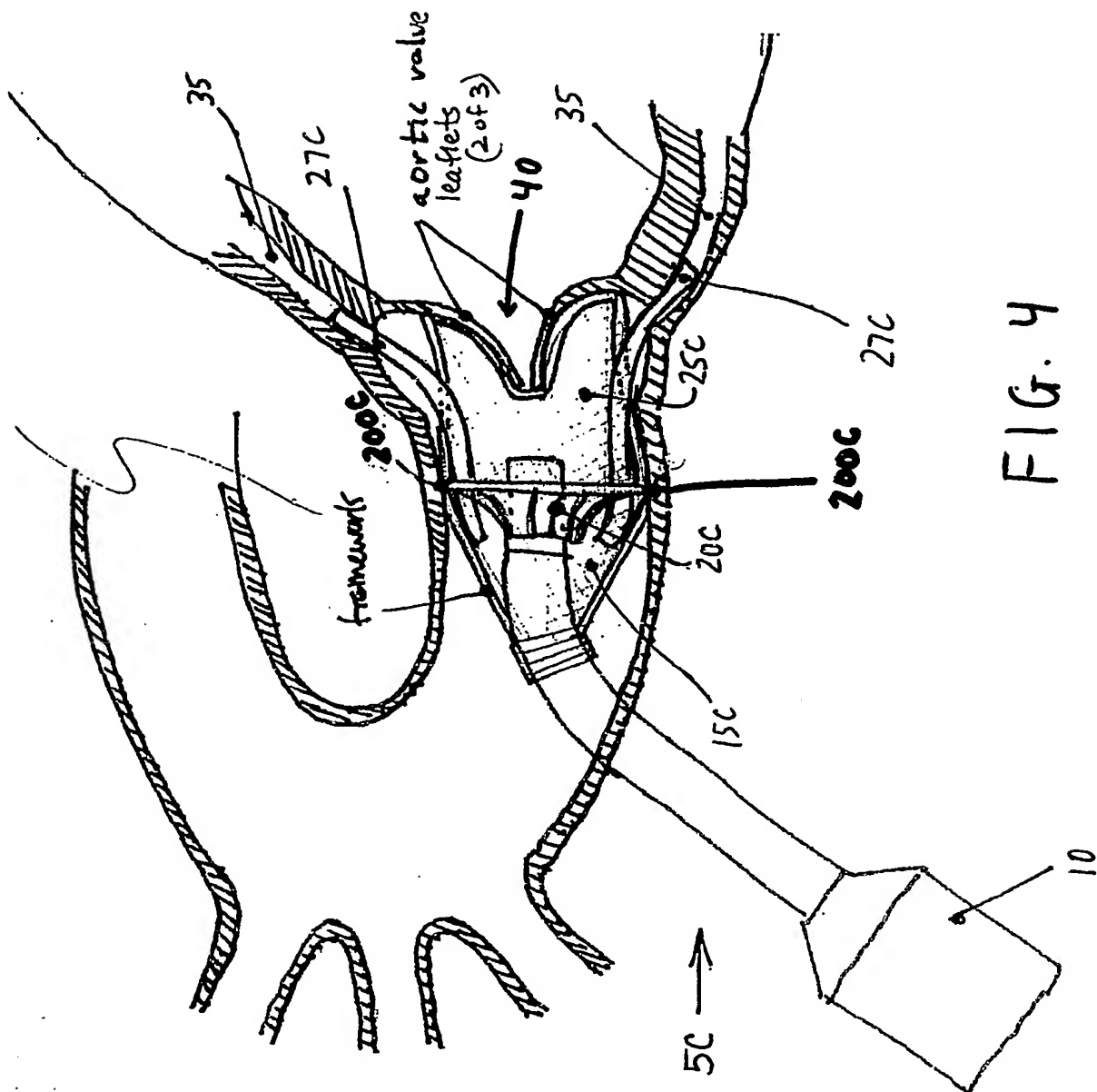
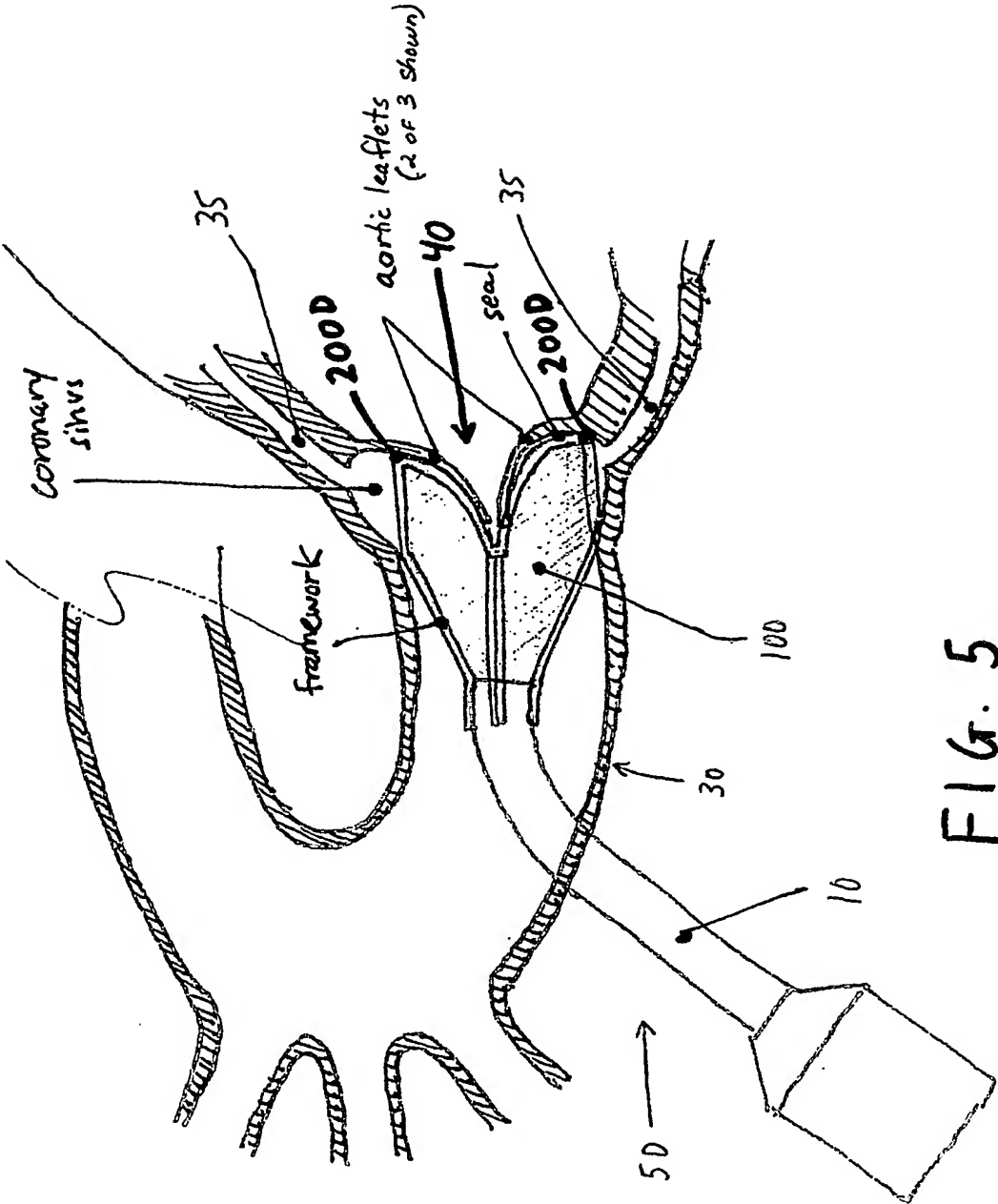


FIG. 3





(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
20 June 2002 (20.06.2002)

PCT

(10) International Publication Number
WO 02/047539 A3

(51) International Patent Classification⁷: **A61M 29/00**

(21) International Application Number: **PCT/US01/48757**

(22) International Filing Date:
14 December 2001 (14.12.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/256,196 15 December 2000 (15.12.2000) US

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(72) Inventor: **STREETER, Richard, B.**; 66 Brookside Avenue, Winchester, MA 01890 (US).

(74) Agent: **PANDISCIO, Mark, J.**; Pandiscio & Pandiscio, 470 Totten Pond Road, Waltham, MA 02451-1914 (US).

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,

CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

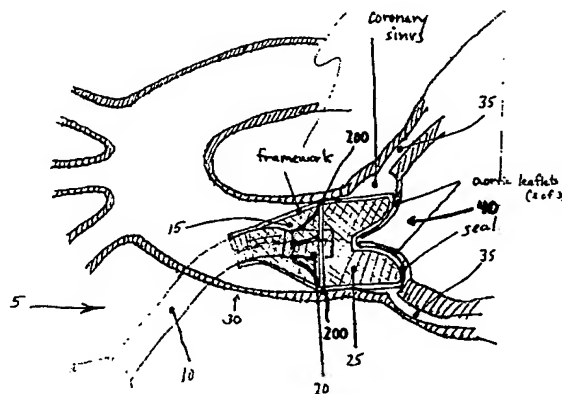
Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

(88) Date of publication of the international search report:
17 October 2002

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: APPARATUS AND METHOD FOR REPLACING AORTIC VALVE



(57) Abstract: Apparatus (5) and methods are disclosed for performing beating heart surgery. Apparatus (5) is disclosed comprising a cannula (10) having a proximal end and a distal end; an aortic filter (15) in connection with the cannula (10), the aortic filter (15) having a proximal side and a distal side; a check valve (20) in connection with the cannula (10), the check valve (20) disposed on the distal side of the aortic filter (15); and a coronary artery filter (25) in connection with the cannula (10), the coronary artery filter (25) having a proximal end and a distal end, and the distal end of the coronary artery filter (25) extending distally away from the distal end of the cannula (10). A method is disclosed comprising providing apparatus (5) for performing beating heart surgery; deploying the apparatus (5) in an aorta; performing a procedure on the aortic valve; and removing the apparatus (5) from the aorta.

WO 02/047539 A3

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US01/44757

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61M 29/00

US CL : 606/200

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/194, 200; 604/6.09

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EAST BRS

search terms: filter, aortic, valve, coronary, valvuloplasty, check

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,769,816 A (BARBUT et al) 23 June 1998, see entire document.	1-23

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

"A"	document defining the general state of the art which is not considered to be of particular relevance	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E"	earlier document published on or after the international filing date	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O"	document referring to an oral disclosure, use, exhibition or other means	"A"	document member of the same patent family
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

19 MAY 2002

Date of mailing of the international search report

05 AUG 2002

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